

REMARKS

Claims 1-11 are pending in this application. Claims 1-11 were variously rejected under 35 U.S.C. § 103.

By this amendment, claims 5-7 have been canceled, claim 1 has been amended, and new claims 12-17 have been added without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment and new claims can be found, *inter alia*, throughout the specification. Support for the amendment to claim 1 is found, *inter alia*, at page 9, paragraph 0031, and in original claims 6 and 7. Support for new claims 12-17 is found, *inter alia*, in Figure 2C, at pages 14-15, paragraphs 0048-0050, and in original claims 8-11.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under 35 U.S.C. §103

Claims 1-11 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Robertson *et al.* (1999, *RNA* 5:1167-1179; "Robertson") or Chappell *et al.* (2000, *Proc. Natl. Acad.*

Sci. USA 97:1536-1541; “Chappell”). Applicants respectfully traverse this rejection to the pending claims.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented herein, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Amended claim 1 is directed to a method to identify an IRES element in which the claimed bicistronic expression system is made intracellular by protoplast fusion. The new claims are directed to a nucleic acid molecule comprising an IRES element where the IRES element sequence is SEQ ID NO:1, 2, 3, 4 or 5, and to methods which use these particular IRES elements.

Both Robertson and Chappell describe transfection as the method for introduction of expression vectors with IRES elements into cells. Neither Robertson or Chappell indicate that the transfection procedures described therein were not suitable for the desired purpose.

Neither Robertson or Chappell describe or suggest the use of protoplast fusion to deliver the test expression system into the cell. As described in the specification, the use of protoplast fusion to deliver the test expression system into cells is a preferred method since it results in near-clonal

delivery of the test system into the cells and can enhance the efficiency of selecting strong IRES elements.¹ The specification also describes that, despite the library of the present invention being more than three orders of magnitude larger than that of Robertson and containing much rarer instances of positive IRES elements, 60-70% of the clones selected by the exemplified method involving protoplast fusion contained the desired IRES activity.²

Although Robertson and Chappell describe IRES elements, neither reference teaches or suggests the specific IRES element sequences taught in the present invention, SEQ ID NOs:1-5.

Further, Applicants respectfully submit that there is no motivation or suggestion in Robertson or Chappell modify the teachings of the references to arrive at the claimed invention.

Thus, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

¹ See, for example, specification page 9, paragraph 0031, and page 13, paragraph 0045.

² See, for example, page 6, paragraph 0022.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 220002063600.

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